



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Friday, June 29, 2007

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 75459-R/ Antibacterial Wipe  
DP Barcode: D336483

To: Velma Noble, PM 31/ Jacqueline Campbell-McFarlane  
Regulatory Management Branch  
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist *IB*  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader *My White Son*  
Chemistry and Toxicology Team *Raven P. Hulse 7/10/07*  
Product Science Branch  
Antimicrobials Division (7510C)

Michele E. Wingfield, Chief  
Product Science Branch  
Antimicrobials Division (7510C)

Applicant: Albaad Massuot Yitzhak, Ltd.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
n-Alkyl Dimethyl Benzyl Ammonium Chloride	0.5
n-Alkyl Dimethyl Ethylbenzyl Ammonium Chloride	0.5
<u>Other Ingredient(s):</u>	<u>99.0</u>
Total:	100.0%

- 1) **BACKGROUND:** Albaad Massuot Yitzhak, Ltd., has submitted a set of five acute toxicity studies to support the data requirements of their product, Antibacterial Wipe.

The five studies were initially reviewed by Agency contractor CSC Systems & Solutions, LLC. The Chemistry and Toxicology Team (CTT) has conducted a brief secondary review to assure compliance with Agency standards.

The submission's cover letter includes a request to waive the acute inhalation toxicity study. The registrant requests the waiver because the product is a wipe.

- 2) **RECOMMENDATIONS:** PSB findings are:

- a) The acute oral and dermal toxicity studies are acceptable.
- b) CTT waives the acute inhalation toxicity study due to the form of the product (wipes/towelettes). In view of this and other toxicological and chemical information, the waiver is accepted.
- c) The primary eye irritation, primary skin irritation and dermal sensitization studies are acceptable.

The acute toxicity profile for File Symbol 75459-R is currently:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity	470126-03	IV	Acceptable
Acute Dermal Toxicity	470126-04	IV	Acceptable
Acute Inhalation Toxicity	None	IV	Waived
Primary Eye Irritation	470126-05	III	Acceptable
Primary Skin Irritation	470126-06	III	Acceptable
Dermal Sensitization	470126-07	Nonsensitizer	Acceptable

- 3) **LABELING:**

- a) The signal word is "Caution".

b) The Precautionary Statements must state:

"Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling or before eating, drinking, chewing gum, using tobacco, or, using restroom."

c) The First Aid Statements must state:

**If in Eyes:**

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for treatment.

**If on Skin or Clothing:**

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a Poison Control Center or doctor for treatment.

**DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (OPPTS 870.1100)**  
(UP AND DOWN PROCEDURE)

**Product Manager:** 31  
**MRID No.:** 470126-03

**Reviewer:** CSC Systems & Solutions LLC  
**Study Completion Date:** June 26, 2006  
**Report No.:** 18825

**Testing Laboratory:** Product Safety Laboratories, East Brunswick, NJ  
**Author:** George E. Moore, B.S.

**Quality Assurance (40 CFR §160.12):** A Quality Assurance statement was included. A statement of Good Laboratory Practice (GLP) compliance also was included stating that the study meets the requirements of 40 CFR Part 160, U.S. EPA (FIFRA), and OECD ENV/MC/CHEM (98)17, with the following exception: specific information related to the stability, identity, strength, purity, and composition of the test substance (as received and as tested) is the responsibility of the study sponsor.

**Test Material:** Antibacterial APC Wipes EX140274  
Lot #: EX140274/9004 / Pre-moistened antimicrobial towelettes

**Dosage:** 5,000 mg/kg (Towelettes were each placed into a 20 mL syringe to expel the liquid from the towelette. The extracted liquid was administered to the animals. The dose was calculated based on the initial body weights, taking into account the specific gravity of the extracted liquid from the test substance.)

**Species:** 3 Sprague-Dawley derived, albino rats  
**Sex:** Female; nulliparous and non-pregnant  
**Age:** Young adult (10 weeks)  
**Weight:** 193-211 grams at experimental start  
**Source:** Ace Animals, Inc., Boyertown, PA  
**Housing:** Temperature Range: 19-22°C  
Relative Humidity: [not provided]  
Photoperiod: 12-hour light/dark cycle

**Acclimation:** 14-15 days

**Conclusion:**

1. **LD<sub>50</sub> (mg/kg):** Female rats >5,000 mg/kg
2. **Toxicity Category:** IV                      **Classification:** Acceptable

**Procedure (Deviations from 870.1100):**

- The laboratory report states that there were no deviations from the final protocol.
- The Certificate of Analysis identifies the test substance as Antibacterial APC Wipes, with Impregnation Lotion EX270163. The Confidential Statement of Formula (CSF; alternate formulation only) and the proposed product label refer to Antibacterial Wipe (401253, EX270163), the name of the product for which registration is being sought. No additional information was provided to link the test substance and the product; however, the two appear to be the same based on the EX270163 designation.

- Individual body weights of test animals were recorded; however, changes in body weights were not reported.
- Information regarding the relative humidity in the animal housing unit was not provided.

**Results:**

Dosing Sequence	Animal No.	Limit Test		
		Dose Level (mg/kg)	Short-Term Outcome	Long-Term Outcome
1	7464	5,000	S	S
2	7471	5,000	S	S
2	7472	5,000	S	S

S – Survival

**Observations:**

All animals survived, gained body weight, and appeared active and healthy during the study. There were no signs of gross toxicity, adverse pharmacologic effects, or abnormal behavior.

**Gross Necropsy Findings:**

No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the 14-day observation period.

## DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (OPPTS 870.1200)

**Product Manager:** 31  
**MRID No.:** 470126-04

**Reviewer:** CSC Systems & Solutions, LLC  
**Study Completion Date:** July 12, 2006  
**Report No.:** 18826

**Testing Laboratory:** Product Safety Laboratories, East Brunswick, NJ  
**Author:** George E. Moore, B.S.

**Quality Assurance (40 CFR §160.12):** A Quality Assurance statement was included. A statement of Good Laboratory Practice (GLP) compliance also was included stating that the study meets the requirements of 40 CFR Part 160, U.S. EPA (FIFRA), and OECD ENV/MC/CHEM (98)17, with the following exception: specific information related to the stability, identity, strength, purity, and composition of the test substance (as received and as tested) is the responsibility of the study sponsor.

**Test Material:** Antibacterial APC Wipes EX140274  
Lot #: EX140274/9004 / Pre-moistened antimicrobial towelettes

**Dosage:** 5,000 mg/kg (The number of patches containing 5,000 mg/kg of liquid per body weight was determined for each animal. The appropriate number of patches were stacked and applied to each dose site.)

**Species:** 10 Sprague-Dawley derived, albino rats  
**Sex:** 5 Males and 5 Females. Females were nulliparous and non-pregnant.  
**Age:** Young adult (8 weeks)  
**Weight:** Males: 284-330 grams; Females: 203-205 grams  
**Source:** Ace Animals, Inc., Boyertown, PA  
**Housing:** Temperature: 19-24°C  
Humidity: [not provided]  
Photoperiod: 12-hour light/dark cycle

**Acclimation:** 15 days

### Summary:

1. **LD<sub>50</sub> (mg/kg):** Male rat: > 5,000 mg/kg  
Female rat: > 5,000 mg/kg
2. **The estimated LD<sub>50</sub> is** greater than 5,000 mg/kg in male and female rats.
3. **Toxicity Category:** IV **Classification:** Acceptable

### Procedure (Deviations from 870.1200):

- The laboratory report indicated that, due to a technical error, the animals in the first test were incorrectly dosed. The test was repeated with a new group of animals using the proper dosage.
- The laboratory report indicated that, due to a technician oversight, the Day 7 body weight for one animal (No. 9892) was not recorded. This deviation did not have any impact on the outcome of the study.

- The Certificate of Analysis identifies the test substance as Antibacterial APC Wipes, with Impregnation Lotion EX270163. The Confidential Statement of Formula (CSF; alternate formulation only) and the proposed product label refer to Antibacterial Wipe (401253, EX270163), the name of the product for which registration is being sought. No additional information was provided to link the test substance and the product; however, the two appear to be the same based on the EX270163 designation.
- Information regarding the relative humidity in the animal housing unit was not provided.

**Results:**

**Reported Mortality**

Dose Level (mg/kg)	Number Dead / Number Tested		
	Males	Females	Total
5,000	0 / 5	0 / 5	0 / 10

**Observations:**

All animals survived exposure to the test substance and gained body weight during the study. Apart from staining (yellow/brown) noted at the dose site of all animals between Days 1 and 14 and females exhibiting ano-genital staining on Day 1, there were no other signs of gross toxicity, adverse pharmacologic effects, or abnormal behavior.

**Gross Necropsy Findings:**

No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the 14-day observation period.

## DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (OPPTS 870.2400)

**Product Manager:** 31  
**MRID No.:** 470126-05

**Reviewer:** CSC Systems & Solutions, LLC  
**Study Completion Date:** June 26, 2006  
**Report No.:** 18827

**Testing Laboratory:** Product Safety Laboratories, East Brunswick, NJ  
**Author:** George E. Moore, B.S.

**Quality Assurance (40 CFR §160.12):** A Quality Assurance statement was included. A statement of Good Laboratory Practice (GLP) compliance also was included stating that the study meets the requirements of 40 CFR Part 160, U.S. EPA (FIFRA), and OECD ENV/MC/CHEM (98)17, with the following exception: specific information related to the stability, identity, strength, purity, and composition of the test substance (as received and as tested) is the responsibility of the study sponsor.

**Test Material:** Antibacterial APC Wipes EX140274  
Lot #: EX140274/9004 / Pre-moistened antimicrobial  
towelettes

**Dosage:** 0.1 mL (Individual towelettes were placed into a 30 mL syringe and the liquid was extracted into a collection vessel. The extracted liquid was then instilled.)

**Species:** 3 rabbits; New Zealand White  
**Sex:** 1 Male and 2 Females  
**Age:** Young adult  
**Weight:** [not provided]  
**Source:** Robinson Services, Inc., Clemmons, NC  
**Housing:** Temperature: 19-24°C  
Humidity: [not provided]  
Photoperiod: 12-hour light/dark cycle

**Acclimation:** 21 days

### Summary:

1. **Toxicity Category:** III
2. **Classification:** Acceptable

### Procedure (Deviations from 870.2400):

- The laboratory report states that there were no deviations from the final protocol.
- The Certificate of Analysis identifies the test substance as Antibacterial APC Wipes, with Impregnation Lotion EX270163. The Confidential Statement of Formula (CSF; alternate formulation only) and the proposed product label refer to Antibacterial Wipe (401253, EX270163), the name of the product for which registration is being sought. No additional information was provided to link the test substance and the product; however, the two appear to be the same based on the EX270163 designation.
- Information regarding the relative humidity in the animal housing unit was not provided.

**Results:**

All animals appeared active and healthy during the study. Apart from the eye irritation noted below, there were no other signs of gross toxicity, adverse pharmacologic effects, or abnormal behavior.

One hour after test substance instillation, all three treated eyes exhibited iritis and conjunctivitis. By 24-hours, two animals developed corneal opacity and a white discharge. The overall incidence and severity of irritation decreased gradually thereafter. All animals were free of ocular irritation by Day 7 (study termination).

The Maximum Mean Total Score of Antibacterial APC Wipes EX140274 is 21.0.

**Incidence of Irritation**

<b>Time Post Instillation</b>	<b>No. of Animals Testing "Positive" / No. of Animals Tested</b>		
	<b>Corneal Opacity</b>	<b>Iritis</b>	<b>Conjunctivae</b>
<b>1 hour</b>	0 / 3	3 / 3	3 / 3
<b>24 hours</b>	2 / 3	3 / 3	3 / 3
<b>48 hours</b>	2 / 3	2 / 3	3 / 3
<b>72 hours</b>	0 / 3	1 / 3	2 / 3
<b>Day 4</b>	0 / 3	0 / 3	2 / 3
<b>Day 7</b>	0 / 3	0 / 3	0 / 3

**Individual Scores for Ocular Irritation**

Observations	Rabbit No. 15897 (Female)					
	Time After Treatment					
	Hours				Days	
	1	24	48	72	4	7
I. Corneal Opacity	0	1 <sup>1</sup>	1	0 <sup>1</sup>	0	0
II. Iris	1	1	1	0	0	0
III. Conjunctivae						
A. Redness	3	3	3	2	1	0
B. Chemosis	2	2	1	0	0	0
C. Discharge	3	2 <sup>2</sup>	2	1	0	0
Observations	Rabbit No. 15898 (Female)					
	Time After Treatment					
	Hours				Days	
	1	24	48	72	4	7
I. Corneal Opacity	0	1 <sup>1</sup>	1	0 <sup>1</sup>	0	0
II. Iris	1	1	1	1	0	0
III. Conjunctivae						
A. Redness	3	3	3	2	1	0
B. Chemosis	2	1	0	0	0	0
C. Discharge	3	1 <sup>2</sup>	1	0	0	0
Observations	Rabbit No. 15899 (Male)					
	Time After Treatment					
	Hours				Days	
	1	24	48	72	4	7
I. Corneal Opacity	0	0 <sup>1</sup>	0	0	0	0
II. Iris	1	1	0	0	0	0
III. Conjunctivae						
A. Redness	3	2	1	0	0	0
B. Chemosis	2	1	0	0	0	0
C. Discharge	3	1	1	0	0	0

<sup>1</sup> 2% ophthalmic fluorescein sodium used to evaluate the extent or verify the absence of corneal opacity.

<sup>2</sup> Discharge, white in color.

## DATA REVIEW FOR ACUTE DERMAL IRRITATION TESTING (OPPTS 870.2500)

**Product Manager:** 31  
**MRID No.:** 470126-06

**Reviewer:** CSC Systems & Solutions, LLC  
**Study Completion Date:** June 26, 2006  
**Report No.:** 18828

**Testing Laboratory:** Product Safety Laboratories, East Brunswick, NJ  
**Author:** George E. Moore, B.S.

**Quality Assurance (40 CFR §160.12):** A Quality Assurance statement was included. A statement of Good Laboratory Practice (GLP) compliance also was included stating that the study meets the requirements of 40 CFR Part 160, U.S. EPA (FIFRA), and OECD ENV/MC/CHEM (98)17, with the following exception: specific information related to the stability, identity, strength, purity, and composition of the test substance (as received and as tested) is the responsibility of the study sponsor.

**Test Material:** Antibacterial APC Wipes EX140274  
Lot #: EX140274/9004 / Pre-moistened antimicrobial towelettes

**Dosage:** Eight 1x1 inch squares of the test substance were stacked on top of each other (per dose site), then applied directly to the skin of the test animals.

**Species:** 3 rabbits; New Zealand White  
**Sex:** 1 Male and 2 Females. Females were nulliparous and non-pregnant.  
**Age:** Young adult  
**Source:** Robinson Services, Inc., Clemmons, NC  
**Housing:** Temperature: 19-23°C  
Humidity: [not provided]  
Photoperiod: 12-hour light/dark cycle  
**Acclimation:** 29 days

### Summary:

1. **Toxicity Category:** III
2. **Classification:** Acceptable

### Procedure (Deviations from 870.2500):

- The laboratory report states that there were no deviations from the final protocol.
- The Certificate of Analysis identifies the test substance as Antibacterial APC Wipes, with Impregnation Lotion EX270163. The Confidential Statement of Formula (CSF; alternate formulation only) and the proposed product label refer to Antibacterial Wipe (401253, EX270163), the name of the product for which registration is being sought. No additional information was provided to link the test substance and the product; however, the two appear to be the same based on the EX270163 designation.
- Information regarding the relative humidity in the animal housing unit was not provided.

**Results:**

All animals appeared active and healthy during the study. Apart from the dermal irritation noted below, there were no other signs of gross toxicity, adverse pharmacologic effects, or abnormal behavior.

One hour after patch removal, all three treated sites exhibited well-defined erythema and slight edema. The overall incidence and severity of irritation decreased gradually with time. Although desquamation was noted for all three animals between Days 7 and 10, the animals were free of erythema and edema by Day 10 (study termination).

The individual Primary (Dermal) Irritation Index was calculated to be 3.3 (which corresponds to the classification of "moderately irritating"). Only scores for observations made during the first 72 hours were used in the calculation.

**Incidence of Irritation**

Time after Patch Removal	Erythema	Edema
<b>30-60 minutes</b>	3 / 3	3 / 3
<b>24 hours</b>	3 / 3	3 / 3
<b>48 hours</b>	3 / 3	3 / 3
<b>72 hours</b>	3 / 3	3 / 3
<b>Day 7</b>	3 / 3	3 / 3
<b>Day 10</b>	0 / 3	0 / 3

**Individual Skin Irritation Scores**

Animal No.	Sex	Erythema / Edema					
		Time After Patch Removal*					
		30-60 min	24 hrs	48 hrs	72 hrs	Day 7	Day 10
<b>15872</b>	<b>F</b>	2 / 2	2 / 1	2 / 1	2 / 1	2 <sup>1</sup> / 1	0 <sup>1</sup> / 0
<b>15873</b>	<b>M</b>	2 / 2	2 / 1	2 / 1	2 / 1	2 <sup>1</sup> / 1	0 <sup>1</sup> / 0
<b>15874</b>	<b>F</b>	2 / 2	2 / 1	2 / 1	2 / 1	1 <sup>1</sup> / 1	0 <sup>1</sup> / 0
<b>Total</b>		6 / 6	6 / 3	6 / 3	6 / 3	5 / 3	0 / 0
<b>Mean</b>		2.0 / 2.0	2.0 / 1.0	2.0 / 1.0	2.0 / 1.0	1.7 / 1.0	0 / 0

<sup>1</sup> Desquamation present at the dose site.

**DATA REVIEW FOR SKIN SENSITIZATION TESTING (OPPTS 870.2600)**  
(BUEHLER METHOD)

**Product Manager:** 31  
**MRID No.:** 470126-07

**Reviewer:** Karen Hicks  
**Study Completion Date:** June 26, 2006  
**Report No.:** 18829

**Testing Laboratory:** Product Safety Laboratories, Dayton, NJ  
**Author:** George E. Moore, B.S.

**Quality Assurance (40 CFR §160.12):** A Quality Assurance statement was included. A statement of Good Laboratory Practice (GLP) compliance also was included stating that the study meets the requirements of 40 CFR Part 160, U.S. EPA (FIFRA), and OECD ENV/MC/CHEM (98)17, with the following exceptions (1) specific information related to the stability, characterization, identity, and composition of the test substance (as received and as tested) is the responsibility of the study sponsor; and (2) the stability, uniformity of mixture, and concentration of the positive control during the historical positive control study were not determined.

**Test Material:** Antibacterial APC Wipes EX140274  
Lot #: EX140274/9004 / Pre-moistened antimicrobial  
towelettes

**Positive Control Material:** alpha-Hexylcinnamaldehyde Technical (HCA)

**Species:** 44 Hartley-albino guinea pigs  
**Sex:** Range Finding: 4 Males  
Test Group: 20 Males  
Naïve Control Group – Challenge: 10 Males  
Naïve Control Group – Rechallenge: 10 Males  
**Age:** Young adult  
**Weight:** Males: 320-460 grams (Test and Challenge/Rechallenge Naïve Control Groups)  
**Source:** Elm Hill Breeding Labs, Chelmsford, MA  
**Housing:** Temperature: 19-21°C  
Humidity: [not provided]  
Photoperiod: 12-hour light/dark cycle  
**Acclimation:** 10-13 days  
**Method:** Buehler Method

**Summary:**

**1. Based on these findings and on the evaluation system used, Antibacterial APC Wipes EX140274 is not considered to be a contact sensitizer.**

**2. Classification:** Acceptable

**Procedure (Deviation from 870.2600):**

- The laboratory report identified the following deviations from the protocol:

- "Due to a technician error, the animals were challenged using the undiluted expressed liquid, instead of a 50% w/w dilution in distilled water, which was selected as the HNIC. Due to the scores of 1 (faint erythema) in both the test and naïve animals, a rechallenge was conducted with the HNIC in accordance with the protocol."
- "Due to a scheduling error, the 24-hour induction scores for the third induction were performed approximately one hour late. This deviation did not affect the outcome of this study."
- The Certificate of Analysis identifies the test substance as Antibacterial APC Wipes, with Impregnation Lotion EX270163. The Confidential Statement of Formula (CSF; alternate formulation only) and the proposed product label refer to Antibacterial Wipe (401253, EX270163), the name of the product for which registration is being sought. No additional information was provided to link the test substance and the product; however, the two appear to be the same based on the EX270163 designation.
- Information regarding the relative humidity in the animal housing unit was not provided.
- Individual body weights of test animals were recorded; however, changes in body weights were not reported.
- Only erythema was graded, and not edema.
- Mineral oil was used as the vehicle in the positive control test; distilled water was used as the vehicle in the main test.

#### **Procedure:**

Preliminary Irritation: A group of animals was used to determine the highest non-irritating concentration (HNIC) of the test substance prior to the challenge dose. The fur was removed by clipping the dorsal area and flanks of each guinea pig. This area was divided into four test sites (two sites on each side of the midline) on each animal. The expressed liquid of the test substance was applied neat and also diluted with distilled water to yield w/w concentrations of 75%, 50%, and 25%. Each concentration was applied (0.4 mL each) to a test site using an occlusive 25 mm Hill Top Chamber. The sites were wrapped with non-allergenic Durapore adhesive tape. After 6 hours of exposure, the chambers were removed and the test sites were gently cleansed of any residual test substance. Approximately 24 hours after application, each site was evaluated for local reactions (erythema) using a scoring system.

From these results, the HNIC (the highest concentration that produced responses in 4 guinea pigs no more severe than two scores of 0.5 and two scores of zero) was established and used for challenge. The HNIC selected for the challenge phase was a 50% w/w mixture in distilled water.

Preparation of Animals: On the day before initiation, the fur of a group of animals was removed by clipping the dorsal area and flanks. After clipping and prior to initiation, the animals were weighed and the skin was checked for any abnormalities. Only healthy animals without pre-existing skin irritation were selected for test. Animals were re-clipped prior to each dose.

Induction Phase: Once each week for three weeks, 0.4 mL of the undiluted expressed liquid was applied to the left side of each test animal using an occlusive 25 mm Hill Top Chamber. The chambers were secured in place and wrapped with non-allergenic Durapore adhesive tape to avoid dislocation of the chambers and to minimize loss of the test substance. After the 6-hour exposure period, the chambers

were removed and the test sites were gently cleansed of any residual test substance. Approximately 24 and 48 hours after each induction application, the animals were scored for a sensitization response (erythema).

Challenge Phase: Twenty-seven days after the first induction dose, 0.4 mL of the undiluted expressed liquid was applied to a naïve site on the right side of each animal as a challenge dose, using the procedures described above. Approximately 24 and 48 hours after the challenge application, the animals were scored for a sensitization response (erythema).

In addition to the test animals, 10 guinea pigs from the same shipment were maintained under identical environmental conditions and were treated with the test substance at challenge only. These animals constituted the Naïve Control Group.

Rechallenge: The wrong concentration of the test substance (100%) was applied at challenge. Therefore, it was necessary to conduct a rechallenge at the appropriate test substance concentration. A rechallenge dose of the test substance at its highest non-irritating concentration (HNIC; determined in the preliminary irritation screen to be a 50% w/w mixture in distilled water) was applied to a naïve site on each test animal and on a new group of naïve control animals. Approximately 24 and 48 hours after the rechallenge application, the animals were scored for a sensitization response (erythema).

Historical Positive Control: The procedures used in this study were validated using HCA as a positive control substance. The most recent validation was completed on October 14, 2005, which is within 6 months of the main study (i.e., study initiation date of December 23, 2005). The test was conducted at the PSL Dayton facility with Hartley-albino guinea pigs from Elm Hill Breeding Labs following induction and challenge procedures similar to those described above.

## **Results:**

### **Induction Phase:**

Test Animals (undiluted expressed liquid from the test substance): Very faint to faint erythema (0.5-1) was noted for all test sites during the induction phase.

Historical Positive Control Animals (HCA applied undiluted): Very faint to faint erythema (0.5-1) was noted for most positive control sites at various intervals during the induction phase.

### **Challenge Phase:**

Test Animals (undiluted expressed liquid from the test substance): Very faint to faint erythema (0.5-1) was noted for nineteen test sites 24 hours after challenge. Similar irritation persisted at seventeen sites through 48 hours.

Naïve Control Animals (undiluted expressed liquid from the test substance): Very faint to faint erythema (0.5-1) was noted for all naïve control sites 24 and 48 hours after the challenge.

Historical Positive Control Animals (75% w/w mixture of HCA in mineral oil): Three of ten positive control animals exhibited signs of a sensitization response (faint to moderate erythema [1-2]) 24 and 48 hours after challenge. Very faint erythema (0.5) was noted for four other sites after challenge.

Historical Naïve Control Animals (75% w/w mixture of HCA in mineral oil): Very faint erythema (0.5) was noted for two of five positive control naïve sites 24 hours after challenge. Irritation persisted at one of these sites through 48 hours.

**Rechallenge Phase:**

Test Animals (50% w/w mixture of the expressed liquid from the test substance in distilled water): Very faint erythema (0.5) was noted for eight of twenty test sites 24 hours after rechallenge phase. Similar irritation persisted at four sites through 48 hours.

Naïve Control Animals (50% w/w mixture of the expressed liquid from the test substance in distilled water): Very faint erythema (0.5) was noted for five of ten naïve control sites 24 hours after rechallenge. Similar irritation was noted at three sites through 48 hours.

**Sensitization Response Indices (Erythema)**

	Incidence of Positive Response <sup>1</sup>		Severity <sup>2</sup>	
	Hours		Hours	
	24	48	24	48
<b>Test Animals – Challenge</b>	5 / 20	3 / 20	0.60	0.50
<b>Naïve Control Animals – Challenge</b>	6 / 10	4 / 10	0.80	0.70
<b>Test Animals – Rechallenge</b>	0 / 20	0 / 20	0.20	0.10
<b>Naïve Control Animals – Rechallenge</b>	0 / 10	0 / 10	0.25	0.15

<sup>1</sup> Animals with scores greater than 0.5.

<sup>2</sup> Sum of the erythema scores divided by the number of animals evaluated.

### Test Animal Group Skin Reaction Scores

Treatment	Induction						Challenge		Rechallenge	
Induction No.	1		2 <sup>1</sup>		3				e	
Concentration	100%		100%		100%		100%		50%	
Hours <sup>2</sup>	24	48	24	48	24 <sup>3</sup>	48	24	48	24	48
Animal No.:										
30352	0.5	0	0.5	1	0.5 <sup>4</sup>	0.5	0.5	0.5	0	0
30353	0.5	0.5	1	1	0.5	1	0.5	0.5	0.5	0
30354	0.5	0.5	0.5	0.5	1	1	1	1	0	0
30355	0.5	1	0.5	1	1	1	0.5	0.5	0	0
30356	0.5	1	1	1	0 <sup>4</sup>	0.5	0.5	0.5	0	0
30357	0.5	0	1	0.5	0 <sup>4</sup>	0	0.5	0.5	0.5	0
30358	0.5	0.5	1	1	1	1	0.5	0	0	0
30359	0.5	0.5	1	0.5	1	1	0.5	0.5	0	0
30360	1	1	1	1	0.5 <sup>4</sup>	0	0.5	0.5	0.5	0.5
30361	0.5	1	0.5	0	1	1	0.5	0.5	0	0
30362	0.5	0.5	0.5	0.5	0.5	1	1	0.5	0.5	0.5
30363	0.5	1	1	1	1	0.5	0.5	0.5	0	0
30364	0.5	0.5	1	1	0 <sup>4</sup>	0.5	0.5	0	0	0
30365	1	1	1	1	0 <sup>4</sup>	0	1	1	0.5	0
30366	0	0.5	1	1	0 <sup>4</sup>	0	1	1	0	0
30367	1	1	0.5	1	1	1	0.5	0.5	0.5	0.5
30368	0.5	0.5	1	1	1	1	0.5	0.5	0	0
30369	0	0.5	1	0.5	1	1	0.5	0.5	0	0
30370	0.5	0.5	0.5	0.5	1	1	0	0	0.5	0
30371	1	0.5	0.5	0.5	1	1	1	0.5	0.5	0.5

<sup>1</sup> All dose sites relocated prior to dosing the 2<sup>nd</sup> induction due to irritation/desquamation.

<sup>2</sup> Hours after induction dose.

<sup>3</sup> Protocol deviation.

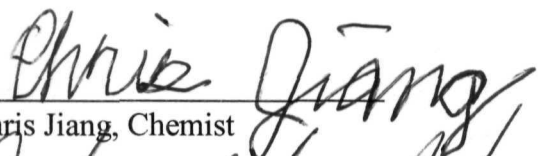
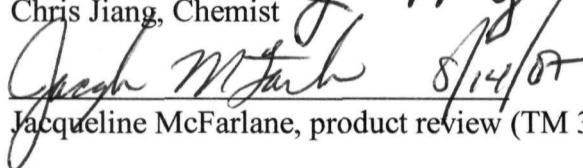
<sup>4</sup> Dose site relocated prior to the 3<sup>rd</sup> induction due to irritation.

August 14, 2007 Scoping Meeting: Discuss Antibacterial Wipe's, EPA File Symbol 75459-R, Chemistry Data

Chris Jiang, chemist, and Jacqueline McFarlane, Team 31 product reviewer, met to discuss the revised confidential statement of formula dated June 15, 2007. Keri Grinstead, Inert Ingredient Assessment Branch, validated that the two hydantoins in the formulations are cleared as inerts in non-food pesticide products. Therefore, the Series 830 data requirements addressed in MRID Nos. 47012601 and 47031101 is acceptable.

The revised Confidential Statement of Formula (CSF) dated June 15, 2007 is acceptable. It is in agreement with the revised label and in compliance with PR Notice 91-2.

The product chemistry data requirements have been fulfilled for Antimicrobial Wipe.

  
Chris Jiang, Chemist  
 8/14/07  
Jacqueline McFarlane, product review (TM 31)

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